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JC17 Rec'd PCT/PTO 21 JUN 2005**AMENDED CLAIMS**

- 1) A process for the preparation of a composite containing a drug dispersed in an organic carrier, wherein the drug is massively dispersed (in bulk) within the particles of said organic carrier and it is present in amorphous form in a quantity greater than or equal to 50%, comprising the following steps:
- a) forming a mixture of a drug with an organic carrier selected from the group consisting of water-soluble complexing agents chosen from cyclodextrins and maltodextrins, water-insoluble cross-linked polymers and mixtures thereof;
- b) irradiating the mixture obtained in a), with microwaves, wherein the microwave power is modulated so that the temperature of the mixture increases until it reaches a value higher than the melting temperature of the drug and it is then maintained constant at said value for at least 5 minutes.
- 2) Process according to claim 1, wherein in step a) a wet mixture is formed by adding a solvent.
- 3) Process according to claim 2, wherein said solvent is water.
- 4) The process according to claim 3, in which said wet mixture is formed by adding water to the carrier-drug composite in a quantity comprised of between 0.1 ml/g and 5 ml/g with respect to the dry mixture of the composite.
- 5) The process according to claims 2 to 4, in which the pressure at which the irradiation is carried out is comprised of between 1 and 20 bar.
- 6) A process according to claims 1 to 4, wherein step b) is carried out in a container constituted of a dielectric material having coupling capacity with the microwaves.
- 7) The process according to claim 6, wherein said dielectric material is polytetrafluoroethylene loaded with graphite.

- 8) The process according to the claims 1 to 7, in which the irradiation with microwaves is carried out in an power range comprised of between 100 W and 5000 W, for an overall time up to 120 minutes.
- 5 9) A process according to claims 1 to 8 wherein said cross-linked polymer is selected from the group consisting of cross-linked polyvinylpyrrolidone, cross-linked sodium carboxymethylcellulose, cross-linked starch, cross-linked dextran, cross-linked polystyrene and cross-linked  $\beta$ -cyclodextrin.
- 10 10) A process according to claims 1 to 9 wherein said drug is a drug sparingly soluble in water.
- 11) A composite containing a drug dispersed in carrier consisting of a water soluble complexing agent selected from cyclodextrins and maltodextrins, wherein the  
15 drug is massively dispersed (in-bulk) within the particles of said complexing agent and it is present in amorphous form in a quantity greater than or equal to 50 % by weight, with respect to the total of drug present in the composite.
- 12) A composite according to claim 10, wherein said cyclodextrins are selected  
20 from alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin and derivatives thereof.
- 13) A composite according to claims 11 or 12, wherein the drug and the carrier are present in weight ratios comprised of between 1:0.5 and 1:20.  
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- 14) A composite according to claim 13, wherein the drug and the carrier are present in weight ratios comprised of between 1:1 and 1:10.
- 15) A composite according to claims 11 to 14, wherein said carrier has a surface  
30 area comprised of between 0.05 m<sup>2</sup>/g and 20 m<sup>2</sup>/g.
- 16) A composite according to claims 11 to 15, wherein said drug is a drug sparingly

soluble in water.

17)A composite according to claim 16, wherein said drug is selected from  
nimesulide, ibuprofen, nifedipine, griseofulvine, piroxicam, progesterone,  
5 lorazepam.

18)A composite as claimed in claims 11 to 17, for use in therapy.

19)A pharmaceutical composition containing a composite as claimed in claims 11  
10 to 18, optionally associated with pharmaceutically acceptable excipients.

20)A pharmaceutical composition according to claim 19, formulated as a  
granulate, pill, mini-pill, capsule, micro-capsule.